IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

This multidistrict litigation (MDL) proceeding consists of, at this point, around 700 individual lawsuits that have been consolidated in this Court for coordinated pretrial proceedings. Each of the lawsuits includes claims for injuries allegedly caused by defendants' testosterone replacement therapy (TRT) drugs.

Before the creation of the MDL proceeding, a significant number of TRT cases were already pending in this district and had been assigned to the undersigned judge for pretrial supervision. The Court determined to consider motions to dismiss in the first few dozen cases that were filed and stayed the filing of responses to the complaints in all cases filed thereafter. On June 4, 2014, the defendants, AbbVie, Inc. and Abbott Laboratories, Inc. (AbbVie), Endo Pharmaceuticals, Inc. (Endo), Auxilium Pharmaceuticals, Inc. (Auxilium), and Lilly USA, Inc. and Eli Lilly and Company (Lilly), jointly moved to dismiss thirty-nine of the complaints under Federal Rule of Civil Procedure 12(b)(6). Endo, Auxilium, and Lilly also separately moved to dismiss the claims against them.

Background

For purposes of the motion to dismiss, the Court accepts as true the following

facts alleged in plaintiffs' complaints. *See, e.g., Fortres Grand Corp. v. Warner Bros. Ent'mt Inc.*, 763 F.3d 696, 700 (7th Cir. 2014). Defendants are manufacturers, sellers, and promoters of TRT drugs, which the Court will refer to as TRTs. TRTs are drugs approved by the U.S. Food and Drug Administration (FDA) for the treatment of abnormally low testosterone in men, a condition known as hypogonadism. 1st Am. Compl. ¶ 29.[1] All of the TRTs at issue in this litigation are administered in the form of a topical cream, gel, or patch. *Id.* ¶ 65.

Plaintiffs allege that defendants fraudulently promoted the drugs for off-label uses and failed to warn plaintiffs and their physicians of potentially dangerous side effects. All of the plaintiffs used AndroGel, manufactured by defendants AbbVie, Inc. and Abbott Laboratories, Inc. Three of the thirty-nine plaintiffs also used a drug manufactured by one of the other defendants. Natale Cataudella used Fortesta, which is manufactured by Endo. Loran Parker used Testim, manufactured by Auxilium. And Frank Lau used Axiron, manufactured by Lilly. Plaintiffs claim that defendants' drugs caused injuries, including blood clots (deep vein thrombosis and pulmonary embolism), heart attacks (myocardial infarctions), and strokes.

A. Off-label promotion allegations

Plaintiffs contend that defendants sought to convince men who did not have hypogonadism "that they suffered from a non-existent and unrecognized medical condition called 'Low T', which was a term for low testosterone." *Id.* ¶ 35. Defendants conducted a "national disease awareness media blitz," which was designed to convince men that "normal and common conditions associated with normal aging could be

[1] Unless otherwise noted, the Court cites to William Blades's amended complaint.

caused by low testosterone levels." *Id.* ¶¶ 35–39. According to plaintiffs, TRTs were promoted as a "lifestyle drug" for off-label uses that were not approved by the FDA, including for treatment of erectile dysfunction, osteoporosis, depression, fatigue, and obesity. *Id.* ¶¶ 47, 49, 63, 92.

Plaintiffs make allegations about each defendant's off-label marketing schemes. Plaintiffs allege that AbbVie intentionally misrepresented information about AndroGel's uses and side effects. Starting in 2000, plaintiffs allege that AbbVie's marketing strategy "has been to aggressively market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products." *Id.* ¶ 89. AbbVie promoted the drug to physicians and healthcare providers "as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms," even though the company knew the drug was not approved for those uses. *Id.* ¶¶ 50, 53. AbbVie operated an unbranded website called "IsItLowT.com," which features an interactive quiz that allows men to determine if they exhibit symptoms of "Low T." *Id.* ¶ 7. In fact, AbbVie was admonished as a result of its promotional efforts in 2000, when the FDA warned that "claims and representation[s] that suggest that AndroGel is indicated for men with 'age associated' hypogonadism or 'andropause' are misleading." *Id.* ¶ 34.

For its part, Lilly's advertisements "suggested that various symptoms often associated with other conditions may be caused by low testosterone." Lau 1st Am. Compl. ¶ 46. Lilly "encouraged men to discuss testosterone replacement therapy with

their doctors if they experienced any of the 'symptoms' of low testosterone." *Id.* Lilly announced in a 2010 press release "that symptoms associated with 'Low T' include 'erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis.'" *Id.* ¶ 60.

Auxilium also engaged in a marketing campaign "for the purpose of increasing and promoting 'off-label' prescriptions for the Testim product." Parker 1st Am. Compl. ¶ 44. Auxilium initiated a "Low Testosterone Therapy With Testim" campaign, and it recruited a professional golfer to provide an endorsement that he had been "successfully" treated for "Low T." *Id.* ¶¶ 48–53. Like AbbVie, Auxilium's website included a questionnaire to promote the product—the "ADAM questionnaire," short for "Androgen Deficiency in Adult Males." *Id.* ¶¶ 56–59. This questionnaire "screened for age-related signs and symptoms," even though the drugs were not approved to treat such symptoms. *Id.* ¶ 58. According to Parker, Auxilium's marketing "was knowingly false, inaccurate, deceptive, and misleading with respect to the information offered," because Auxilium "willfully sought to conflate the diagnosis of hypogonadism with the diagnosis of 'Low T' or age-related declines in testosterone levels or age-related symptoms in men." *Id*.

Endo also embraced the "Low T" moniker. Cataudella 1st Am. Compl. ¶ 42. Endo disseminated advertisements encouraging men to see their doctors about symptoms including "'reduced sexual drive (libido) and activity,' 'difficulty in achieving or maintaining an erection,' feeling 'tired, fatigued, or notic[ing] a loss of energy,' depressed mood, 'lost body hair or . . . less of a need to shave,' 'decrease in strength or muscle mass,' or osteoporosis." *Id.* ¶ 47. Endo also stated in a 2011 press release that

the symptoms of "Low T" include "'erectile dysfunction and decreased sexual desire.'" *Id.* ¶ 63. Like the other defendants, Endo operated a website, www.GetTestedForLowT.com, which encouraged men "to complete a quiz to see if they are 'eligible for a free testosterone test to measure [their] testosterone levels.'" *Id.* ¶ 48. Endo provided free blood testing to men as long as state law did not prohibit the testing. *Id.* ¶ 54.

B. Injury allegations

Plaintiffs cite a number of studies that purport to show that TRTs increase users' risks for cardiac events, stroke, pulmonary embolisms, and blood clotting. 1st Am. Compl. ¶¶ 105–08. According to the plaintiffs, TRT drugs increase hematocrit, the proportion of total blood volume that is comprised of red blood cells, and estradiol, the primary female sex hormone. Increases in hematocrit and estradiol, they allege, can result in blood clots, strokes, and other cardiovascular events. *Id*. ¶¶ 66–81.

Plaintiffs allege that defendants "purposefully downplayed, understated and outright ignored the health hazards and risks associated with using" TRTs. *Id.* ¶ 93; Lau 1st Am. Compl. ¶ 103; Cataudella 1st Am. Compl. ¶ 107; Parker 1st Am. Compl. ¶ 126. Plaintiffs contend that the prescribing information and medication guides for AndroGel, Fortesta, Testim, and Axiron do not adequately warn about potentially dangerous side effects. Specifically, they fail to instruct patients to tell their healthcare providers about traits that increase the risk of blood clotting, and they fail to instruct patients and physicians to screen for preexisting conditions that increase the risk of clotting and heart disease. 1st Am. Compl. ¶¶ 97, 100. The prescribing information and medication guides also fail to instruct physicians to evaluate patients' hematocrit and estradiol

levels. *Id.* ¶ 99, 102.

To support the contention that defendants' warnings were insufficient, plaintiffs refer to a June 19, 2014 announcement by the FDA that it was requiring TRT manufacturers to update their labels to include a general warning about the risks of venous thromboembolism, including deep vein thrombosis and pulmonary embolism. *Id.* ¶ 110.

Each plaintiff alleges that he was injured as a result of taking testosterone replacement therapy. Each also states that he would not have taken defendants' drugs or would have monitored for side effects had he known of the risks. Plaintiffs assert claims for: (1) strict products liability based on failure to warn; (2) negligence; (3) breach of implied warranty; (4) breach of express warranty; and (5) fraud. Some also assert claims for design defect, negligent misrepresentation, and loss of consortium. *See, e.g.*, 1st Am. Compl. ¶¶ 188–206. Two complaints also include a wrongful death or survival action because the plaintiff is now deceased. *See* LaRoche 1st Am. Compl. ¶¶ 194–200; Lueck 1st Am. Compl. ¶¶ 167–75.

Defendants have collectively moved to dismiss the complaints. Defendants Endo, Lilly, and Auxilium have also separately moved to dismiss the claims against them. Because the allegations against each of the defendants are nearly identical, the Court will not address Endo, Lilly, and Auxilium's motion to dismiss separately. The Court will, however, discuss the specific allegations against each defendant where relevant.

Discussion

When considering a motion to dismiss under Federal Rule of Civil Procedure

12(b)(6), the Court accepts the plaintiffs' allegations as true and draws reasonable inferences in their favor. *Parish v. City of Elkhart*, 614 F.3d 677, 679 (7th Cir. 2010). In order to state a viable claim, the plaintiffs must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face if "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Defendants make global arguments that apply to all of the plaintiffs' claims. The Court will address the issues raised in the motion to dismiss that are common to plaintiffs' products liability, fraud, and warranty claims. With the exception of Michigan and Texas, the two states in which defendants contend relief is completely barred, the Court will not address defendants' state law arguments at this stage.

A. Causation

Defendants argue that plaintiffs' claims should be dismissed for failure to plead causation sufficiently. The Court disagrees.

Defendants contend that plaintiffs have not plausibly alleged that TRTs caused their injuries. Defendants argue that the scientific studies on which plaintiffs rely have been discredited and that the connection between TRTs and plaintiffs' injuries has not been conclusively proven. But it is inappropriate to assess the weight of the evidence at the motion to dismiss stage. "[T]he plausibility requirement demands only that a plaintiff provide sufficient detail to present a story that holds together." *Alexander v. United States*, 721 F.3d 418, 422 (7th Cir. 2013) (internal quotation marks omitted).

As support for their causation argument, plaintiffs cite scientific studies and the

FDA's recent requirement that all TRT manufacturers change their labels to warn about the risk of venous thromboembolism. Accepting these allegations as true and making reasonable inferences in favor of the plaintiffs, the plaintiffs have sufficiently alleged general causation. *See Mohr v. Targeted Genetics, Inc.*, 690 F. Supp. 2d 711, 719–21 (C.D. Ill. 2010) (denying motion to dismiss as to causation when the FDA found the warnings to be inadequate after plaintiff's injury).

Defendants also argue that the injuries were more likely caused by common age-related risk factors and that each plaintiff has failed to plead enough information about his medical history and risk factors. Again, plaintiffs need only plead enough factual detail to make their claims plausible. The plausibility requirement does not require defendants' drugs be the most likely cause of the plaintiffs' injuries, as defendants assert. "'Plausibility' for purposes of Rule 8 is not synonymous with 'probability'; it is not, for instance, necessary (or appropriate) to stack up inferences side by side and allow the case to go forward only if the plaintiff's inferences seem more compelling than the opposing inferences." *Alexander*, 721 F.3d at 422 (internal quotation marks omitted). Plaintiffs need not dispel all alternative causes at this stage; they need only "provide sufficient detail to present a story that holds together." *Id.* (internal quotation marks omitted).

Although the complaints contain varying degrees of detail, each plaintiff has identified the injury he suffered, when the injury occurred, and which drug he used. Each plaintiff also alleges that he had no history of such problems. 1st Am. Comp. ¶ 114. Plaintiffs' medical histories will be revealed over the course of the litigation. They have pled their claims with enough detail to allow a reasonable inference that

there was a causal relationship between their use of TRTs and their injuries.

B. Failure to warn

Defendants next contend that all claims premised on a failure to warn theory should be dismissed under the learned intermediary doctrine. Manufacturers of products generally have a duty to warn potential users of foreseeable risks. Forty-eight states, the District of Columbia, and Puerto Rico, have recognized an exception to this general rule, referred to as the learned intermediary doctrine, which applies when a physician or third party prescribes the product. *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806–09 (E.D. Tex. 2002) (surveying the learned intermediary doctrine as applied in each state). Under the learned intermediary doctrine, "a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider." Restatement (Third) of Torts: Prods. Liab. § 6 cmt. e. Defendants argue that plaintiffs allege nothing about what materials their physicians reviewed and how different warnings would have altered their decisions to prescribe the drug. Defendants also contend that the warnings in the drugs' prescribing information and medication guides that existed at the time of injury preclude a claim based on failure to warn.

Plaintiffs' central contention is that the warnings provided to plaintiffs and their physicians were not adequate. The adequacy of warnings is generally considered a factual issue. *See, e.g., Baker v. Bayer Healthcare Pharm., Inc.*, No. C13-0490 TEH, 2013 WL 6698653, at *3 (N.D. Cal. Dec. 19, 2013). "[B]ased solely on the allegations contained in the amended complaint, there appears to be a factual dispute as to the adequacy of the warnings and whether they informed the medical community of all risks

known at the time." *Mohr*, 690 F. Supp. 2d at 719. Because plaintiffs have plausibly alleged that defendants' warnings are inadequate, the Court denies the motion to dismiss claims premised on a failure to warn theory. *See Smith v. Boehringer Ingelheim Pharm., Inc.*, 886 F. Supp. 2d 911, 920–23 (S.D. Ill. 2012) (denying motion to dismiss failure to warn claims where prescribing information and label warned that "'PRADAXA can cause serious and, sometimes, fatal bleeding,'" because "the plaintiff alleges (among other things) that BIPI failed to adequately warn about the increased risk of excessive or uncontrollable bleeding in patient's taking Pradaxa").

The Court next addresses defendants' specific arguments related to failure to warn. Defendants point out that the prescribing information already warns that an increase in hematocrit may increase the risk of thromboembolic, or clotting, events. For this reason, they assert, the claims of plaintiffs who suffered blood clots should be dismissed. AndroGel's prescribing information does warn that "[i]ncreases in hematocrit . . . may require lowering or discontinuation of testosterone," and that "[a]n increase in red blood cell mass may increase the risk of thromboembolic events." Defs.' Mem. Supp. Mot. to Dismiss, Ex. 4 at 40.[2] The prescribing information also states that it would "be appropriate to re-evaluate the hematocrit 3 to 6 months after starting treatment." *Id.* Axiron, Fortesta, and Testim carry similar warnings. Defs.' Mem. Supp. Mot. to Dismiss, Ex. 5 at 72 (Axiron), 83 (Fortesta), 110 (Testim).

[2] "Documents attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to his claim." *Adams v. City of Indianapolis*, 742 F.3d 720, 729 (7th Cir. 2014) (internal quotation marks omitted), *cert. denied*, 135 S. Ct. 286 (2014). Plaintiffs' complaints refer to the prescribing information and medication guides contained within the package materials of defendants' TRTs, 1st Am. Compl. ¶ 96, and these documents are central to their claims. The Court can therefore consider the prescribing information and medication guides, which defendants have attached to their motion to dismiss.

Plaintiffs claim, however, that the prescribing information and label did not adequately warn physicians and users of potential risks of increased hematocrit. They allege that defendants did not warn that hematocrit "can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction," and that stroke, transient ischemic attack, cardiovascular disease, myocardial infarction, and coronary heart failure are related risks. 1st Am. Compl. ¶¶ 96, 98.

Defendants also contend that the prescribing information already warns about the risk of blood clots. But this does not require dismissal of plaintiffs' failure to warn claims. Although AndroGel and Fortesta's medication guides warned that testosterone may cause "blood clots in the legs," the warning does not mention clots in other parts of the body. 1st Am. Compl. ¶ 101; Defs.' Mem. Supp. Mot. to Dismiss, Ex. 4 at 63 (AndroGel 1%), Ex. 5 at 95 (Fortesta), 151 (AndroGel 1.62%). Additionally, the label does not instruct physicians to monitor for certain conditions that increase the risk of blood clots, and it does not warn about an increased risk of pulmonary embolism. 1st Am. Compl. ¶¶ 97–98, 100–03. And the label does not warn that TRTs can increase estradiol levels, which can result in blood clotting. *Id.* ¶¶ 102–03. Plaintiffs thus allege a number of ways in which the label inadequately warned about the risk of blood clotting.

Defendants contend that Cataudella's complaint must be dismissed because he was over the age of sixty-five when he began using TRTs, and the prescribing information warns that there is insufficient safety and efficacy data for patients over the age of sixty-five. Defs.' Mem. Supp. Mot. to Dismiss, Ex. 4 at 67 (AndroGel 1%), Ex. 5

at 73 (Axiron), 86 (Fortesta). But plaintiffs claim that defendants failed to warn that men over sixty-five who use TRTs have an increased risk of heart attack. Cataudella 1st Am. Compl. ¶ 118. Again, because plaintiffs have pointed plausibly to a way in which the warnings were inadequate, Cataudella's claims based on failure to warn will not be dismissed.

Defendants argue that plaintiffs failed to specify which materials their healthcare providers reviewed and why a different warning would have prevented the doctor from prescribing the drug. As one court has stated in a similar case, however, "it is difficult to know, prior to discovery, whether [plaintiff's] physician would have prescribed [the drug] if there were additional warnings." *Mohr*, 690 F. Supp. 2d at 718. Plaintiffs have plausibly alleged that defendants' failure to provide adequate warnings would have had an impact on healthcare providers' decisions to prescribe TRTs.

The Court denies defendants' motion to dismiss plaintiffs' failure to warn claims.

C. Fraud and negligent misrepresentation

Defendants contend that plaintiffs' fraud and negligent misrepresentation claims should be dismissed under Federal Rule of Civil Procedure Rule 9(b), which requires a party alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Plaintiffs do not dispute that their fraud and negligent misrepresentation claims must be stated with particularity. They contend that their complaints meet the requirements of Rule 9(b).

To satisfy Rule 9(b), plaintiffs must specify "the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." *Gen. Elec.*

Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1078 (7th Cir. 1997). In this case, the plaintiffs have adequately pled the "the who, what, where, and when of the alleged fraud." *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999).

Plaintiffs have stated the "who": they contend that defendants misrepresented the safety and approved uses of TRTs in communications directed at plaintiffs and their physicians. As to the "what," plaintiffs allege that these misrepresentations were in the form of television advertisements, website content, and other marketing communications. In terms of the content of the misrepresentations, plaintiffs contend that "Low T" was a fake disease concocted by defendants, who sought to give men the false impression that TRTs were approved to treat conditions like erectile dysfunction, osteoporosis, depression, fatigue, and obesity. 1st Am. Compl. ¶ 169. In encouraging men to be screened for "Low T," defendants allegedly mischaracterized the medical data and symptoms of hypogonadism. *Id.* ¶ 44, 120. The defendants also allegedly misrepresented the approved uses of the drugs through their online quizzes—AbbVie's "www.IsItLowT.com," Auxilium's "ADAM questionnaire," and Endo's "www.GetTestedForLowT.com"—all of which were designed to make men think that normal signs of aging were symptoms of "Low T." According to plaintiffs, these misrepresentations were made "knowingly, falsely, deceptively, and inaccurately." *Id.* ¶ 172.

Plaintiffs have identified a number of allegedly false or misleading statements made by each defendant:

- Lilly's statement that "up to 13 million men over 45 years of age in the U.S. may have symptoms associated with low testosterone." Lau 1st Am. Compl. ¶ 40.

- Lilly's statement that "AXIRON is used to treat adult males who have low or no testosterone.'" *Id.* ¶ 41.
- Lilly's statement "that symptoms associated with 'Low T' include 'erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis.'" *Id*. ¶ 60.
- Auxilium's advertisements in which a professional golfer stated that he was "successfully" treated for "Low T." Parker 1st Am. Compl. ¶¶ 48–53.
- Endo's advertisements that described symptoms including "reduced sexual drive (libido) and activity," "difficulty in achieving or maintaining an erection," feeling "tired, fatigued, or notic[ing] a loss of energy," "lost body hair or . . . less of a need to shave," and "decrease in strength or muscle mass." Cataudella 1st Am. Compl. ¶ 47.
- Endo's press release stating that the symptoms of "Low T" include "erectile dysfunction and decreased sexual desire." *Id.* ¶ 63.
- AbbVie's 2001 statement that "four to five million American men" suffer from hypogonadism and its 2003 statement that "up to 20 million men" suffer from the disease. 1st Am. Compl. ¶ 31.
- The questions on AbbVie's online quiz, including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", "Are you sad and/or grumpy?", and "Do you have a lack of energy?" *Id.* ¶ 37.

In addition to identifying specific misrepresentations, plaintiffs have also sufficiently pled fraud by omission. They allege that defendants failed to disclose the

risks of stroke, pulmonary embolism, and cardiovascular events and that they knew or should have known about these side effects. Contrary to defendants' arguments, plaintiffs have not merely repackaged their failure to warn claims as fraud and warranty claims. Plaintiffs do more than allege injury due to defendants' failure to warn. Rather, they contend that defendants engaged in a scheme to deceive the public by fabricating a nonexistent disease. The fraud and negligent misrepresentation claims are thus distinct from the failure to warn claims. *See James v. Stryker Corp.*, No. 1:10-CV-2082, 2011 WL 292240, at *1 (M.D. Pa. Jan. 27, 2011) (internal citation omitted) ("Plaintiff asserts that her fraud claim arises out of Defendants perpetrating a fraud upon the medical community and Plaintiff by means of unlawful, off-label promotions. Because the Court agrees with Plaintiff that her fraud claim is not based on a failure to warn theory, the Court will deny Defendants' motion to dismiss.").

Plaintiffs also have alleged enough about the relevant time period, the "when," to survive defendants' motion to dismiss. Although they do not state the exact date they or their physicians heard or read a misrepresentation, they identify the date each drug was approved, the time period in which defendants promoted the drug, and the date each plaintiff suffered injury. Most of the complaints also state the date the drug was prescribed. Plaintiffs' allegations are sufficient to satisfy the temporal requirement of Rule 9(b). They do not need to state the precise date on which they saw or read an advertisement to adequately plead fraud. *See Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 737 (7th Cir. 2014) (noting that Rule 9(b) does not "require that [the plaintiff] provide the precise date, time, and location that he saw the advertisement or every word that was included on it"); *Hornbeck v. Medtronic, Inc.*, No. 13 C 7816, 2014

WL 2510817, at *5 (N.D. Ill. June 2, 2014) (denying motion to dismiss fraud claims where "[t]he Complaint details an elaborate campaign to manipulate the medical community as to the safety and efficacy of a use of the InFUSE® Bone Graft component that the FDA did not approve"); *Smith*, 886 F. Supp. 2d at 927.

In a distinguishable case cited by defendants, the Seventh Circuit required plaintiffs to state dates of misrepresentations or omissions, when they alleged a fraudulent scheme by insurance agents to induce customers to purchase large policies without disclosing the fact that much of the value would go to the agent's commission. *Ackerman*, 172 F.3d at 470. Unlike in this case, the insurance agents made face-to-face representations to the plaintiffs, and thus plaintiffs' lawyers could readily determine "the approximate date of the fraud, since the date the policy was issued to the particular client would appear on the copy of the policy in the client's possession." *Id.* Plaintiffs in this case, on the other hand, allege that they and their physicians heard or saw advertisements on the television or Internet some time before they were prescribed the drug. It would be unnecessarily burdensome to require the plaintiffs to identify, for pleading purposes, the exact date on which they heard or saw a particular representation. The Court concludes that plaintiffs have adequately pled the who, what, where, and when of the alleged fraud and negligent misrepresentation.

Defendants also argue that plaintiffs did not adequately plead reliance on the alleged misrepresentations. Each plaintiff states that he relied on defendants' claims, 1st Am. Compl. ¶¶ 181–82, and Rule 9(b) does not require plaintiffs plead reliance in greater detail. A plaintiff need not demonstrate "reliance on the defendant's misrepresentations or omissions, and the reasonableness of that reliance" to satisfy

Rule 9(b). *Midwest Commerce Banking Co. v. Elkhart City Ctr.*, 4 F.3d 521, 524 (7th Cir. 1993).

Defendants also point out that many of the plaintiffs began using TRTs before 2012. According to defendants, because AbbVie's fraudulent advertising allegedly occurred in 2012, plaintiffs who decided to use the drug before then could not have relied on those representations. But plaintiffs provide numerous examples of advertising and marketing before 2012. In 2000, the FDA warned AbbVie that "claims and representation[s] that suggest that AndroGel is indicated for men with 'age associated' hypogonadism or 'andropause' are misleading." 1st Am. Compl. ¶ 34. Plaintiffs also refer to a 2009 whistleblower lawsuit that alleged AndroGel was marketed and promoted for off-label uses. *Id.* ¶ 47. And the complaint refers to a "2004 memo on AndroGel sales strategies." *Id.* ¶ 43. Although defendants' 2012 advertising campaigns serve as an example of defendants' deceptive marketing, plaintiffs allege fraudulent marketing that spanned many years.

In sum, plaintiffs have adequately pled claims for fraud and negligent misrepresentation.

D. Express warranty

Defendants contend that plaintiffs' express warranty claims should be dismissed because they have not identified any express warranty. Plaintiffs cite one court's denial of a motion to dismiss an express warranty claim against a pharmaceutical manufacturer. There, the express warranty consisted of statements that the drug was "well-tolerated," "safe," and "fit" to treat the condition, which were distributed through "conventions for medical professionals, package inserts, promotional and other written,

oral, and electronically disseminated statements." *Rosenstern v. Allergan, Inc.*, 987 F. Supp. 2d 795, 805 (N.D. Ill. 2013) (internal quotation marks omitted). In that case, the plaintiffs quoted language that allegedly constituted an express warranty. Here, by contrast, plaintiffs have pointed to no statement that constitutes an express warranty.

Plaintiffs essentially contend that the same statements that constitute fraud also constitute express warranties. But plaintiffs must plead more than misstatements and omissions to state a claim for breach of express warranty. To state a claim for breach of express warranty in every state at issue, plaintiffs must point to a specific affirmation or promise on which the plaintiffs relied. *See* U.C.C. § 2-313; *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig*., 687 F. Supp. 2d 897, 905 (W.D. Mo. 2009) (noting that "[e]very state has adopted the Uniform Commercial Code" and applying U.C.C. § 2-313 to express warranty claims consolidated in a multidistrict litigation), *clarified on den. of recons.*, No. 08-1967-MD-W-ODS, 2010 WL 286428 (W.D. Mo. Jan. 19, 2010). *See also Brady v. Medtronic, Inc.*, No. 13-CV-62199-RNS, 2014 WL 1377830, at *8 (S.D. Fla. Apr. 8, 2014) (Florida law); *Smith v. Hartz Mountain Corp.*, No. 3:12-CV-00662, 2012 WL 5451726, at *4 (N.D. Ohio Nov. 7, 2012) (Ohio law); *Horsmon v. Zimmer Holdings, Inc*., No. CIV.A. 11-1050, 2011 WL 5509420, at *4 (W.D. Pa. Nov. 10, 2011) (Pennsylvania law); *McCauley v. Hospira, Inc.*, No. 1:11CV108, 2011 WL 3439145, at *6 (M.D.N.C. Aug. 5, 2011) (North Carolina law); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 216 (E.D.N.Y. 2004) (New York law); *Williams v. Beechnut Nutrition Corp*., 185 Cal. App. 3d 135, 142, 229 Cal. Rptr. 605, 608 (1986) (California law).

Because plaintiffs have not made allegations sufficient to describe an express

warranty, the Court dismisses their express warranty claims, with leave to amend. The Court does not address at this point the other arguments made by defendants in support of dismissal of these claims.

E. Implied warranty

Although plaintiffs' implied warranty claims are not labeled, plaintiffs appear to bring claims for breach of implied warranty of merchantability.[3] They contend that defendants warranted that their products were "safe and fit" to treat "Low T," even though the products were "neither safe for [their] intended use nor of merchantable quality." 1st Am. Compl. ¶¶ 160, 162.

Under the Uniform Commercial Code, a seller who is a merchant with respect to the type of goods sold impliedly warrants that the goods are merchantable, which as relevant here means that the goods "are fit for the ordinary purposes for which such goods are used," "are adequately contained, packaged, and labeled as the agreement may require," and "conform to the promise or affirmations of fact made on the container or label." U.C.C. § 2-314. In many states, a plaintiff can bring a claim for implied warranty of merchantability if the manufacturer's warnings or labels were defective and those defects caused the plaintiff's injury. *See DiBartolo v. Abbott Labs*., 914 F. Supp.

[3] The implied warranty of fitness for a particular purpose does not appear to apply in this case. Under the Uniform Commercial Code, the implied warranty of fitness requires that the "buyer is relying on the seller's skill or judgment to select or furnish suitable goods." U.C.C. § 2-315. Here, the plaintiffs did not rely on the drug manufacturers to select particular drugs for them. *See Woodill v. Parke Davis & Co.*, 58 Ill. App. 3d 349, 355, 374 N.E.2d 683, 688 (1978) (concluding that an action for implied warranty of merchantability can be brought by a patient against a drug manufacturer, but not an action for implied warranty of fitness). Additionally, the implied warranty of fitness requires the item be purchased for "a specific use by the buyer which is peculiar to the nature of his business." U.C.C. § 2-315, cmt. 2. There is currently no allegation that defendants' TRTs were purchased for a use that was particular to the plaintiffs.

2d 601, 627 (S.D.N.Y. 2012) (New York law); *Sec. Nat. Bank of Sioux City, Iowa v. Abbott Labs.*, No. 11-CV-4017-DEO, 2012 WL 327863, at *18 (N.D. Iowa Feb. 1, 2012) (Iowa law); *Collins v. Pfizer, Inc.*, No. 1:08-CV-0888-DFH-JMS, 2009 WL 126913, at *4 (S.D. Ind. Jan. 20, 2009) (Indiana law); *Woodill v. Parke Davis & Co.*, 58 Ill. App. 3d 349, 356, 374 N.E.2d 683, 688 (1978), *aff'd and remanded*, 79 Ill. 2d 26, 402 N.E.2d 194 (1980) (Illinois law).

Without delving into the specifics of different states' laws, plaintiffs have sufficiently pled claims for breach of the implied warranty of merchantability. They plausibly allege that they believed, based on defendants' misrepresentations and inadequate warnings, that TRTs were safe and effective for the treatment of "Low T." *See DiBartolo*, 914 F. Supp. 2d at 627. The Court defers ruling on state-specific issues, including the application of the learned intermediary doctrine and states' privity requirements to plaintiffs' warranty claims, for the reasons described in more detail below. Accordingly, defendants' motion to dismiss the plaintiffs' implied warranty claims is denied.

F. Loss of consortium

Because the Court denies defendants' motion to dismiss as to most of their common claims, defendants' motion to dismiss the derivative loss of consortium claims is also denied.

G. State law issues

Defendants argue that individual states' laws bar some or all of plaintiffs' claims. A transferee court is not required to make case-specific rulings in the place of the transferor court. Some MDL transferee courts have concluded that

> such case-specific rulings are neither the purpose, nor the forte, of a court presiding over a multi-district litigation. A MDL seeks to promote judicial economy and litigant efficiency by allowing the transferee court to preside over matters common among all cases. [ ] Given this function, the transferee court typically does not rule on cumbersome, case-specific legal issues.

In re Nuvaring Prods. Liab. Litig., No. 4:08MD1964 RWS, 2009 WL 4825170, at *2 (E.D. Mo. Dec. 11, 2009) (internal quotation marks omitted); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, No. 11 C 5468, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012). Though this Court does not necessarily subscribe to that reasoning in its entirety, the Court concludes that it makes sense to address differences in state law only to the extent that this would reduce the discovery burden in a material way. *See In re Nuvaring Prods. Liab. Litig*., 2009 WL 4825170, at *2. With the exception of Michigan and Texas, the two states in which defendants contend relief is completely barred, defendants will have to engage in discovery for cases involving every other state at issue. In other words, it does not appear that rulings favorable to the defendants concerning the particulars of other state law claims would reduce in a material way the overall burden of discovery. Accordingly, with the exception of Michigan and Texas, the Court defers deciding individual state law issues.[4]

1. Choice of law

Before addressing Michigan and Texas law, the Court must address the question of choice of law. Defendants contend that the law of the place of the plaintiff's injury applies. Plaintiffs do not directly dispute this point; instead, they argue that the Court should not determine the applicable substantive law at this stage because discovery

[4] The Court reserves the right to consider individual state law issues at later points during the MDL proceeding, including on summary judgment or when the Court considers exemplar cases.

might shed light on the analysis. Because the complaint alleges enough information for the court to determine the applicable substantive law and one state bars plaintiffs' claims, the Court will determine the applicable substantive law.

In an MDL proceeding, "a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the thirty-nine actions at issue in this motion were filed in the Northern District of Illinois, Illinois choice of law rules govern.

Illinois has adopted the approach of the Second Restatement of Conflict of Laws. To determine which state has the most significant interest as required under the Second Restatement, the Court must apply a "'two-step process in which the court (1) chooses a presumptively applicable law under the appropriate jurisdiction-selecting rule, and (2) tests this choice against the principles of § 6 in light of relevant contacts identified by general provisions like § 145 (torts) and § 188 (contracts).'" *Townsend v. Sears, Roebuck & Co.*, 227 Ill. 2d 147, 164, 879 N.E.2d 893, 903 (2007) (quoting P. Borchers, *Courts and the Second Conflicts Restatement: Some Observations and an Empirical Note*, 56 Md. L. Rev. 1232, 1247 (1997)).

The law of the place of the injury presumptively applies to plaintiffs' tort claims unless another jurisdiction has a more significant relationship with the occurrence and the parties. *See Townsend*, 227 Ill. 2d at 163, 879 N.E.2d at 903; Restatement (Second) of Conflicts of Law § 146 (1971) (law of the state of the injury presumptively applies in a personal injury action); *id.* § 148 cmt. a ("In situations where [ ] false representations result in physical injury to persons . . . the applicable law is selected by

application of [§ 146]."). Testing this presumption against the general principles identified in section 6 and section 145 of the Second Restatement, no other jurisdiction has a more significant relationship.

Section 145 instructs the Court to consider "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." Restatement (Second) of Conflicts of Law § 145. Applying those factors, the complaints specify each plaintiff's state of residence and citizenship at the time he used the drugs and was injured. 1st Am. Compl. ¶ 11. It is reasonable to infer that defendants' drugs caused injury in each plaintiff's state of residence and that plaintiffs and their physicians heard any misrepresentations in that state. As to the other choice of law factors, the defendants are domiciled in and incorporated under the laws of different states, the conduct that caused the injury likely occurred in many states, and the parties have no existing relationship. Those factors are therefore inconclusive. The general factors under section 6 also tilt in favor of applying the law of the plaintiff's state of residence, as that state has a significant interest in having the personal injury claims of its citizens litigated under its laws.[5] Accordingly, the presumption that the law of the plaintiff's state

[5] Section 6 requires the Court to consider

> (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied.

Restatement (Second) of Conflict of Laws § 6.

of residence applies to his tort claims has not been rebutted.

The choice of law analysis differs for plaintiffs' warranty claims, because in Illinois each issue is subject to a separate choice of law analysis. *See Townsend*, 227 Ill. 2d at 161, 879 N.E.2d at 901–02. To determine the applicable substantive law for claims sounding in contract or quasi-contract, the Court must consider "(a) the place of contracting, (b) the place of negotiation of the contract, (c) the place of performance, (d) the location of the subject matter of the contract, and (e) the domicil, residence, nationality, place of incorporation and place of business of the parties." Restatement (Second) of Conflict of Laws § 188. There were no negotiations or written contracts in this case. Thus, the parties' domicile and residence weighs heavily in the choice of law analysis. Any warranties were presumably heard or seen in the plaintiff's state of residence, and it does not appear that the defendants' states of incorporation or principal places of business have a significant interest in the action. Thus, the law of each plaintiff's state or residence will also apply to his warranty claims.

2. Michigan

A Michigan statute bars any "product liability action" against a drug manufacturer or seller "if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller." Mich. Comp. Laws § 600.2946(5). Unless a statutory exception applies, "a manufacturer or seller of a drug that has been approved by the FDA has an *absolute defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the

manufacturer or seller." *Taylor v. Smithkline Beecham Corp.*, 468 Mich. 1, 7, 658 N.W.2d 127, 131 (2003) (emphasis added).

This defense applies to all of plaintiff Kenneth Montgomery's claims, because Michigan defines a "product liability action" broadly to mean "an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product." Mich. Comp. Laws § 600.2945(h). "Production" includes, among other things, "design, . . . warning, instructing, marketing, selling, advertising, packaging, or labeling." *Id.* § 600.2945(i). All of Montgomery's claims, including his fraud and warranty claims, seek relief for injuries related to AbbVie's inadequate warnings or misrepresentations made in the course of "marketing, selling, [and] advertising" the drugs. *Id.* Even though the fraud and warranty claims appear to be distinct from the failure to warn claims, they are nonetheless subject to the statutory bar. *See Att'y Gen. v. Merck Sharp & Dohme Corp.*, 292 Mich. App. 1, 4–14, 807 N.W.2d 343, 345–50 (2011) ("We hold that when, as here, the drug in question was approved by the FDA, the state's suit to recover Medicaid money premised on fraud by the drug company in its representations regarding the safety and efficacy of the drug is barred by MCL 600.2946(5)."); *Albrecht v. Fort Dodge Animal Health, Inc.*, No. 12-11429, 2013 WL 823325, at *2 (E.D. Mich. Mar. 6, 2013) (dismissing implied warranty claims based on the Michigan statute), *aff'd*, No. 13-1425 (6th Cir. Oct. 17, 2013).

The Michigan statute sets forth three exceptions, which apply when a drug manufacturer (1) sold the drug in the United States after the FDA ordered the drug's removal from the market or withdrew its approval; (2) intentionally withheld or

misrepresented information to the FDA that was required to be submitted, and the drug would not have been approved or approval would have been withdrawn if accurate information had been submitted; or (3) made an illegal payment to an FDA official or employee to secure or maintain approval of the drug. *Id*. The first and third exceptions are not applicable—the FDA has not removed AndroGel from the market or withdrawn its approval, and plaintiffs do not claim that defendants bribed FDA officials.

The application of the exception for intentional misrepresentation to the FDA is disputed. The amended complaint[6] alleges that AbbVie falsely represented to the FDA that approximately one million men suffer from hypogonadism, 1st Am. Compl. ¶ 30, but it does not squarely allege that this misrepresentation affected the FDA's approval of the drug. Reading this into the amended complaint would stretch the concept of reasonable inference beyond what is appropriate. The Court therefore dismisses Montgomery's complaint with leave to amend but will nonetheless address the applicability of the statutory exception, on the assumption that his or other Michigan plaintiffs' complaints will be amended to squarely allege the exception's applicability.

There are two federal appellate-level decisions interpreting the statutory misrepresentation-to-the-FDA exception. In *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit considered a challenge to section 600.2946(5) by a plaintiff who contended the statute was impliedly preempted by the federal Food, Drug and Cosmetic Act and that it violated due process because it deprived her of a remedy for her injuries. The plaintiff's primary contention was that the Michigan statute

[6] Unlike the other plaintiffs, Montgomery appears not to have filed an amended complaint, for reasons that are unexplained. The Court assumes for present purposes that he could and would file an amended complaint consistent with those filed by the other plaintiffs against AbbVie.

requires her to prove fraud on the FDA in order to sustain a claim; a claim of fraud on the FDA is preempted by federal law; and thus the Michigan statute is itself preempted. The Sixth Circuit was therefore required to consider the impact of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court ruled that a state law claim of fraud on the FDA was impliedly preempted by federal law because it would in effect require state-by-state enforcement of the FDA's regulatory scheme and thus would inevitably conflict with the FDA's responsibility to police fraud consistently with the agency's judgment and objectives. *Id.* at 347–53. In *Garcia*, the court noted that the Michigan statute did not establish a cause of action requiring fraud on the FDA but rather provided immunity for drug manufacturers with an exception for cases involving fraud on the FDA. It concluded that the difference was immaterial, because "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Garcia*, 385 F.3d at 966 (internal quotation marks omitted). The court determined, however, that federal law does not preempt the Michigan statutory exception in all of its applications; it concluded that if the FDA itself had found fraud in a particular situation, there would be no preemption of a state-law claim. *Id.* Thus, the court concluded, the Michigan statute was unconstitutional (because of preemption) in some settings but not others. The court therefore determined not to invalidate the statute in its entirety, based on Michigan's general rule of severability of invalid portions of statutes. *Id.* at 966–67. Thus under *Garcia*, a plaintiff to whom Michigan law applies has a claim in these circumstances only if the FDA itself has found fraud—which would mean that the claims of any plaintiff in this case to whose claims Michigan law applies are barred. *See also*

Marsh v. Genentech, Inc., 693 F.3d 546, 549–52 (6th Cir. 2012) (reaffirming *Garcia*); *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012) (determining that a similar Texas statute is preempted unless the FDA itself has found fraud).

The other federal appellate-level decision addressing the Michigan statute is the Second Circuit's decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), and it stands in opposition to *Garcia*. The court in *Desiano* began with the longstanding presumption against implied preemption of state law claims. *Id.* at 93 (citing *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996)) ("Congress does not cavalierly pre-empt state-law causes of action."). *Buckman* concluded that this presumption did not apply to a state law fraud-on-the-FDA claim because "'policing fraud against federal agencies is hardly a field which the States have traditionally occupied,'" *id.* (quoting *Buckman*, 531 U.S. at 347), but the Second Circuit concluded that the Michigan statute did not represent "a state's attempt to police fraud against the FDA." *Id.* at 94. The Michigan statute did not create a cause of action premised on fraud on the FDA; rather it restricted recovery under existing state products liability law. This objective, the court concluded, was within the state's "prerogative to regulate matters of health and safety," which is an area in which the presumption against federal preemption is strong. *Id.* (internal quotation marks omitted). The plaintiff in *Desiano*, the court noted, was not pressing a claim of fraud on the FDA but rather was pursuing a claim under traditional state tort law. *Buckman*, the court concluded "cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA." *Id.* at 95.

The court cited Michigan law indicating that reliance on section 600.2946(5) is a defense to liability, and it concluded that "[f]inding preemption of traditional common law claims where fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past." *Id.* at 96. The court therefore rejected the Sixth Circuit's reading of the statute.

Under *Desiano*, unlike *Garcia*, a finding by the FDA that it has been defrauded is not a prerequisite to relief. This Court finds the analysis in *Desiano* more persuasive than that in *Garcia*. Among other things, *Garcia* seems to turn somersaults—reading a limitation into the statutory exception that it does not contain—in order to preserve the overall preclusion of products liability claims against the plaintiff's preemption attack.

For these reasons, if Montgomery and other plaintiffs whose claims are governed by Michigan law can, consistent with Federal Rule of Civil Procedure 11(b), plausibly allege that the defendants intentionally withheld or misrepresented information to the FDA in a way that affected the agency's approval of the drug, their cases will be permitted to proceed.

3. Texas

Texas is the only other state that defendants argue completely bars any of the first thirty-nine plaintiffs' claims. Contrary to defendants' arguments, the Texas plaintiffs' claims are not barred. In Texas, a defendant in a products liability action alleging injury caused by a failure to warn is presumptively insulated from liability if the warnings were approved by the FDA or the warnings provided were those developed by the FDA that may be distributed without an approved new drug application. Tex. Civ. Prac. & Rem.

Code Ann. § 82.007. The statute lists five exceptions that allow the plaintiff to rebut this presumption. The third exception, for off-label promotion, applies in this case. Under that exception, a plaintiff can rebut the presumption of immunity if the defendant (A) "recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration," (B) the plaintiff used the product "as recommended, promoted, or advertised," and (C) the "injury was causally related to the recommended, promoted, or advertised use of the product." *Id.* § 82.007(b)(3).

The plaintiffs have alleged facts sufficient to raise a plausible claim for off-label promotion under Texas law. First, they contend that defendants promoted their drugs for treatment of "Low T," a fabricated disease, to treat conditions for which the drugs were not approved. Second, plaintiffs claim that they took the drug to treat symptoms attributable to low testosterone. Third, each plaintiff alleges that he suffered injury as a result of taking the drug that he would not have suffered had he been adequately warned. *See Murthy v. Abbott Labs.*, No. 4:11-CV-105, 2012 WL 6020157, at *4 (S.D. Tex. Dec. 3, 2012). Plaintiffs have adequately pled a claim for off-label promotion under Texas law.

Defendants incorrectly contend that the FDA itself must find fraud in order to rebut the presumption of non-liability in Texas. Defendants rely on the Fifth Circuit's decision in *Lofton*, discussed in the Michigan-law section of this decision. *Lofton*, however, addressed a different statutory exception, namely section 82.007(b)(1), which allows a claimant to rebut the presumption of immunity when the defendant withheld or misrepresented relevant information from the FDA. Tex. Civ. Prac. & Rem. Code Ann.

§ 82.007(b)(1). The Fifth Circuit held that "§ 82.007(b)(1) is preempted unless the FDA itself has found fraud," because "where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities." *Lofton*, 672 F.3d at 380. The court, however, addressed only the fraud exception. Contrary to defendants' argument, the other statutory exceptions do not require a finding of fraud. *Id*. at 380–81.

For these reasons, the Texas plaintiffs' claims are not subject to dismissal.

4. Other states

Although many of the other states' laws differ with respect to the types of claims plaintiffs may bring, none of them completely bars plaintiffs' lawsuits. Because the defendants will in any event be required to produce discovery for claims governed by the law of these states, the Court will not dismiss other claims on state law grounds.

The Court accepts Mark King's withdrawal of his negligent misrepresentation claim. Pls.' Resp. to Defs.' Mot. to Dismiss at 42 n.42.

Conclusion

For the foregoing reasons, the Court grants defendants' motions to dismiss in part [dkt. nos. 66 & 72]. The Court grants the motion to dismiss as to Kenneth Montgomery's complaint, with leave to amend. The Court also grants the motion to dismiss as to each plaintiff's express warranty claim. The motion to dismiss is otherwise denied. Counsel for plaintiffs and defendants are directed to promptly confer in order to present to the Court prior to the next case management conference a proposal concerning the timing of defendants' responses to the remaining complaints and how

defendants may preserve in those responses points the Court has rejected and specific state-law arguments the Court has declined to address at this juncture.

MATTHEW F. KENNELLY
United States District Judge

Date: December 23, 2014